

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 38, 47-51, 53, 56-66, 68-69, 74-78, 80-82, 84-89, 94-104, 106-107, 112-116, 118-121, 123-128, 130, 133-143, 145-146, 151-155, 157-159 and 163-209 are pending in the application, with 38, 84, 123, 167, 185, and 196 being the independent claims. Claims 39-46, 52, 54-55, 67, 70-73, 79, 83, 90, 92-93, 105, 108-111, 117, 122, 129, 131-132, 144, 147-150, 156, and 160-162 have been cancelled without prejudice to or disclaimer of the subject matter therein. Claims 38, 84, 123, 163, 164, and 166, have been amended. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and further request that they be withdrawn.

Summary of the Invention

The claimed invention is directed to ***CTL epitopes of C35***. These epitopes are useful for diagnosis, prognostic testing, and treatment of C35-specific cancers such as breast cancer. The elected species is a polypeptide or fusion protein comprising the CTL-inducing epitope ITNSRPPCV.

Information Disclosure Statement

According to the Office Action, copies of many of the documents listed on the Information Disclosure Statement (IDS) filed October 16, 1002 (Paper 15) were not found in the PTO file. As evidenced by the attached copy of date-stamped postcard, copies of these documents were filed along with the IDS. Nonetheless, for the Examiner's convenience, new copies of these documents will be provided shortly.

Rejections under 35 U.S.C. § 112, first paragraph - written description

Claims 38-46, 81, 83, 84, 119, 121-123, 158, and 160-166 were rejected under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter that was not described in such a way as to reasonably convey that the inventors had possession of the claimed invention when the application was filed. Paper 22, at p. 3. Applicants respectfully traverse the rejection.

The pending claims define a structural feature common to members of the genus.

Compliance with the written description requirement does not require a patent specification to describe exactly the claimed subject matter; rather, the specification must show the skilled artisan that the applicant invented what is claimed. *See Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000) ("The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed'"(citations omitted)).

Relative to biotechnology inventions,

[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, . . . or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

University of California v. Eli Lilly and Co., 43 USPQ2d 1399, 1406 (Fed. Cir. 1997) (emphasis added).

Moreover, *functional* descriptions of biological material can satisfy the written description requirement if a structure/function correlation is known in the art. *See Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003) ("Eli Lilly did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure" (citation omitted)). Importantly, the Federal Circuit has said, in reference to the recitation of known biological materials, "[b]oth *Eli Lilly* and *Enzo Biochem* are inapposite to this case because the claim terms at issue here are not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend." *Amgen Inc. v. Hoechst Marion Roussel Inc.*, at 1332.

Additionally, the description only needs to describe what is new or not conventional. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94; MPEP 2163, p. 2100-165, col. 2 (Rev. 1, Feb. 2003).

Claim 38 and dependent claims

Although respectfully disagreeing with the rejection, Applicants have nevertheless amended claim 38 to expedite prosecution. As amended, claim 38, and the claims depending therefrom, recite a polypeptide comprising at least one of a number of specific epitopes, wherein the polypeptide is at least 95% identical to a fragment of C35 (SEQ ID NO:2). As acknowledged by the Examiner, the specification may adequately describe a genus even though it fails to describe a single species falling within the genus. MPEP 2163 (II)(A)(3)(a)(ii) at p. 2100-169, col. 1. In this case, however, the specification describes numerous species falling within the genus, for example, in paragraphs [0064], [0073], [0076], [0078], and [0079], Tables 1-6 (pages 33-179). Each species within the scope of the claim has at least 95% identity with the reference sequence, and contains a recited epitope of C35. Therefore, the claims are adequately described. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claim 84 and dependent claims

Concerning claim 84 and the claims depending therefrom, Applicants point out that numerous fusion proteins are described in the specification. Fusion proteins described in the specification include fusions comprising combinations of C35 epitopes, fusions comprising a heterologous peptide, fusions comprising part of the constant domain of an immunoglobulin, fusions comprising an MHC molecule, fusions comprising a signal sequence, and fusions comprising a marker sequence. For example, see pages 203-204, 220-222, and Example 8 on pages 261-263. Applicants did not need to provide the sequences of the heterologous sequences because they are known. *See*

Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d at 1384, 231 USPQ at 94; MPEP 2163, p. 2100-165, col. 2 (Rev. 1, Feb. 2003).

Importantly, contrary to the assertion at page 5 of the Office Action, these fusion proteins do **not** need to have the same function as a wild type C35 polypeptide, as they comprise the recited CTL epitopes that are useful in diagnosis, prognostic testing, and treatment of C35-specific cancers. The specification recognizes that such proteins may have these uses in the absence of full length C35 functions, for example, at paragraphs [0064] and [0077]. In addition, the specification generally describes the use of epitopes in cancer treatment in the Background Art section, and describes the use of the C35 epitopes of the invention in cancer diagnosis, prognostic testing and treatment at numerous places in the Detailed Description and Examples. *See, for example*, pages 32-33, 179-181, 201-202, and 211-216. In Example 2 on pages 227-229, the inventors have shown that CTLs specific for a C35 epitope kill breast cancer cells. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claim 123 and dependent claims

Concerning claim 123 and the claims depending therefrom, Applicants point out that these claims do not encompass fragments longer than the recited epitopes, nor do they encompass fusion proteins. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph - enablement

Claims 38-46, 81, 83, 84, 119, 121-123, 158, and 160-166 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly being nonenabled for their full scope. Paper 22, p. 6.

The Office Action stated that the claimed molecules:

may possess function that is not commensurate with the functions of the native protein. The variant amino acids may not maintain the activities proposed in the specification. It would seem that specific function(s) would be required to make the encoded protein useful for . . . treating breast and bladder carcinomas.

Paper 22, p. 6. Applicants respectfully traverse.

Again, as emphasized above, the claimed polypeptides and fusion proteins do ***not*** need to have the same function as a wild type C35 polypeptide. The claimed polypeptides and fusion proteins comprise CTL epitopes that are useful in diagnosis, prognostic testing, and treatment of C35-specific cancers. The specification describes these uses throughout the specification. And in Example 2 on pages 227-229, the inventors have shown that CTLs specific for a C35 epitope kill breast cancer cells.

Furthermore, one of ordinary skill in the art would not doubt the enablement of the pending claims due to the state of the art and the level of ordinary skill in the art. For example, evidence of the level of skill regarding fusion proteins comes from an article published *eleven years ago*, describing the use of fusion proteins comprising epitopes (referred to as a "string of beads" vaccine) to induce protective immunity against a viral challenge. J.L. Whitten, *et al.*, *J. Virol.* 67:348-352 (January 1993) (abstract attached).

The state of the art has advanced a considerable degree since that article published, and prior to the earliest filing date for the present claims. Therefore, the present claims are enabled for their full scope.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, are respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 38-46, 81, 122, 158, 160, 161, 163, and 166 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. patent application publication no. US2002/0052308A1. Paper 22, p. 8. Applicants respectfully traverse the rejection.

The pending claims are directed to a polypeptide comprising at least one of a list of particular epitopes, wherein the polypeptide is 95% identical to a fragment of C35 (SEQ ID NO:2), and to a fusion protein comprising at least one of a list of particular epitopes.

The cited publication, US2002/0052308A1, does not disclose the claimed invention. US2002/0052308A1 discloses a protein 131 amino acids in length (SEQ ID NO:966). However, contrary to the Examiner's assertion, Applicants were unable to find any specific description of the epitope ITNSRPPCV, or any of the other epitopes recited in the present claims, anywhere in the cited publication. In the absence of a specific teaching or suggestion to make these particular epitopes, the cited publication cannot anticipate or render obvious the claimed invention. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 38-46, 81, 83, 84, 119, 121, 122, 158, and 160-166 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. patent application publication no. US2002/0052308A1. Paper 22, p. 9. Applicants respectfully traverse the rejection.

As mentioned above, Applicants were unable to find any specific description of the epitope ITNSRPPCV, or any of the other epitopes recited in the present claims, anywhere in the cited publication. In the absence of a specific teaching or suggestion to make these particular epitopes, the cited publication cannot anticipate or render obvious the claimed invention. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and request that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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